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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,956	09/18/2003	Maria Alexandra Glucksmann	MPI00-368P1RCN1M	8337

7590 07/06/2005

MILLENNIUM PHARMACEUTICALS, INC.
Intellectual Property Department
75 Sidney Street
Cambridge, MA 02139

EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1649

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,956

Applicant(s)

GLUCKSMANN ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 47-52 and 72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 47-52 72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

1) Claims 1 to 22, 47 to 52 and 72 are pending in the instant application. Claims 23 to 46 53 to 71 and 73 to 104 have been canceled as requested by Applicant in the correspondence filed 18 September of 2003.

2) Claims 11 and 13 to 21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. See M.P.E.P. 608.01(n)III.

3) Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 to 7 and 12, drawn to an isolated polynucleotide and method of use, classified in class 435, subclass 69.1.
- II. Claims 8 to 10, drawn to an isolated polypeptide, classified in class 530, subclass 350.
- III. Claim 11, drawn to an antibody, classified in class 530, subclass 388.22.
- IV. Claims 13, 14, 32 and 33, drawn to a method of detecting a polypeptide in a sample, classified in class 436, subclass 501.
- V. Claim 15, drawn to a kit comprising a compound of unspecified constitution which specifically binds to a polypeptide, classified in class 530, subclass 388.22, for example.

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- VI. Claims 16 to 18, 23, 28, 47 to 51 and 72, in so far as they are drawn to a kit containing a nucleic acid probe and a method of detecting a nucleic acid in a sample, classified in class 435, subclass 6.
- VII. Claims 19, 20, 22, 47 to 52 and 72, in so far as they are drawn to a receptor binding assay, classified in class 435, subclass 7.21, for example.
- VIII. Claim 21, drawn to a method of modulating the activity of a protein by administering a compound of unspecified constitution, classification undeterminable.

The inventions are distinct, each from the other because:

The polynucleotide that is invention I, the polypeptide that is invention II, the antibody that is invention III, the binding agent of unspecified constitution that is invention V and the polynucleotide probe that is invention VI are five structurally and functionally different chemical compounds each of which can be made and used without any one or more of the other compounds. Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Inventions III and V are related to inventions IV and VIII as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

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instant case the products that are inventions III and V can be used in the two materially different processes that are inventions IV and IX. The processes of inventions IV and IX are materially different because they achieve different objects by employing different method steps. Inventions are materially different if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The host cell included in invention I and the isolated polypeptide of invention II are each related to the binding assay of invention VII as product and process of use. They are shown to be distinct because the process, as claimed, can be practiced with either an intact cell or an isolated protein, which are two materially different products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
PRIMARY EXAMINER
GROUP 1800